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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,465	12/09/2003	Jeffrey A. Whitsett	10872/0507287	5274

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FROST BROWN TODD, LLC
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EXAMINER

MONTANARI, DAVID A

ART UNIT	PAPER NUMBER
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1632

NOTIFICATION DATE	DELIVERY MODE
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11/05/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

dbell@fbtlaw.com
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Office Action Summary

Application No.

10/731,465

Applicant(s)

WHITSETT ET AL.

Examiner

David Montanari

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39,40 and 42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39,40 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/11/2007.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/11/2007 has been entered.

-Claims 1-38,41 and 43-75 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/27/2006.

1. The rejection of claims 39, 40 and 42 under Double Patenting is withdrawn in view of Applicants approved Terminal Disclaimer.
2. The rejection of claims 39, 40 and 42 under 35 USC 112, first paragraph, new matter is withdrawn in view of Applicants amendments.
3. Claim 39 is amended.
4. Claims 39, 40 and 42 are examined in the instant application.

Claim Rejections - 35 USC § 112

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39, 40 and 42 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record in the office actions mailed on 4/11/2007 and 7/14/2006.

Response to Arguments

Applicant argue in amendment filed on 10/11/2007 that in response to the telephone interview on 10/10/2007, amendments were made to the claims to address issues of enablement concerning the claimed method. Applicant continues that the claimed method has been amended now to recite that only airway hyperresponsiveness and/or airflow limitation associated with respiratory disease involving an inflammatory response in a subject will be treated. Applicant continues that previously submitted declarations (Glasser and Whitsett) detail the link between SP-C deficiency and disease as well as the feasibility of treatment. Applicant continues that they have submitted an additional eleven references demonstrating the link between SP-C protein and the treatment of pulmonary disease, and that several of these references demonstrate the feasibility of therapy with SP-D and SP-B for acute diseases as tested in mice or sheep. Applicant continues that surfactant protein administration for acute respiratory distress syndrome in premature infants has been successful for many years in clinical practice. These arguments are not persuasive.

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While Applicant has amended the claims to narrow to the treatment of a specific pulmonary disorder, the cited references and previous declarations do not overcome the rejections of record. It is noted again that the specification is silent with regard to any guidance to be provided to the skilled artisan as to enable the treatment of airway hyperresponsiveness and/or airflow limitation associated with respiratory disease involving an inflammatory response. The specification rather is drawn to the generation and characterization of SP-C transgenic mice, which comprise targeted disruptions in the SP-C gene thus interfering with SP-C production and designed to mimic SP-C deficiency. The recently supplied references further do not provide enablement for the claimed method as they only detail again a link between SP-C deficiency and particular pulmonary pathologies and disorders. The linkage between SP-C deficiency and its effects in patients is not an issue here, rather the treatment of airway hyperresponsiveness and/or airflow limitation associated with respiratory disease involving an inflammatory response. The references provided by Applicant and the previously submitted Glasser and Whitsett declarations do not teach the skilled artisan how to treat airway hyperresponsiveness and/or airflow limitation associated with respiratory disease involving an inflammatory response in a patient. Rather said references and declarations provide only that SP-C administration may be a potential therapeutic. Specific issues of enablement with respect to the treatment of pulmonary disorders in general have been addressed in previous Office Actions. While Applicant has narrowed the claimed method to airway hyperresponsiveness and/or airflow limitation associated with respiratory disease involving an inflammatory response, these issues of record remain. Thus for reasons of record and above the rejection is maintained.

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No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108.

The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David A. Montanari, Ph.D.

/Anne-Marie Falk/
Anne-Marie Falk, Ph.D.
Primary Examiner, Art Unit 1632